IN THE UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF MISSOURI
WESTERN DIVISION

TEDENE and ROBERT LACHANCE,	)	
	)	
Plaintiffs,	)	
	)	
vs.	)	Case No. 01-0890-CV-W-ODS
	)	
AMERICAN HOME PRODUCTS CORPORATION, et al.,	)	
	)	
	)	
Defendants.	)	

ORDER AND OPINION GRANTING IN PART DENYING IN PART DEFENDANTS' MOTION FOR PARTIAL SUMMARY JUDGMENT

Pending is Defendant Wyeth's Motion for Partial Summary Judgment (Doc. # 29). For the following reasons, the Motion is granted in part and denied in part.

I. BACKGROUND

Plaintiffs Tedene and Robert Lachance ("Plaintiffs") filed this products liability action in May 2001 against Defendants American Home Products Corporation, Wyeth Laboratories, Inc., Wyeth-Ayerst Laboratories, Inc., and A.H. Robins Company, Incorporated (collectively "Defendants"). Plaintiffs are citizens of Missouri. American Home Products Corporation (AHPC) is a Delaware corporation with its principal place of business in New Jersey. A.H. Robins Company was merged into AHPC in 1998 and no longer exists as a separate entity. Wyeth Laboratories was merged into Ayerst Laboratories Inc in 1999. The surviving company's name was changed to Wyeth-Ayerst Pharmaceuticals Inc ("WAPI") and is an unincorporated division of AHPC.

AHPC marketed, distributed and sold Pondimin to licensed health care providers in the United States, including Nebraska and Missouri. Pondimin is an anorectic drug indicated for the management of obesity. The United States Food and Drug Administration ("the FDA") approved Pondimin as safe and effective for the treatment of obesity in accordance with its FDA-approved prescribing information, and subject to the

warnings, precautions and contraindications stated therein in 1973. As part of the approval process, Wyeth Laboratories submitted clinical testing and other required data to the FDA and was thereafter subject to the FDA's enforcement powers. The FDA oversees the post-market surveillance for an approved drug, and the manufacturer is required to submit post-market surveillance information to the FDA.

In 1983, Wyeth Laboratories added information regarding Primary Pulmonary Hypertension (PPH) to the Pondimin label. It stated the patient should immediately report any deterioration of exercise tolerance, a common symptom of PPH. The label was revised again in 1987, expanding the PPH information and stating that a fatality had occurred. In 1994, the label was reviewed and approved by the FDA. The label was changed again in 1996 based on the results of an International Primary Pulmonary Hypertension Study. That same year, three letters were sent from Wyeth to physicians indicating the risk of PPH associated with the use of Pondimin.

Pondimin was prescribed in combination with phentermine and has been referred to as "fen-phen." Pondimin has been prescribed independently and in combination with phentermine. In September 1997, Pondimin was withdrawn from the market.

On June 14, 1995, Tedene Lachance consulted with Dr. Linda Babbitt. Dr. Babbitt prescribed Pondimin and phentermine for Ms. Lachance. Ms. Lachance took Podimin until May 1997. While taking Pondimin, Ms. Lachance estimates she lost 25 pounds. On March 11, 2000, an echocardiogram demonstrated Ms. Lachance suffered from aortic valve thickening, aortic regurgitation, mitral valve thickening, tricuspid regurgitation, and increased pulmonary artery pressures or primary pulmonary hypertension.

Plaintiffs allege ten claims against Defendants: (1) fraudulent misrepresentation, (2) negligent misrepresentation, (3) failure to warn, (4) failure to test, (5) negligence, (6) negligence per se, (7) strict liability, (8) breach of express warranty, (9) breach of implied warranty, and (10) violation of unfair trade practices.

II. DISCUSSION

1. Standard

A moving party is entitled to summary judgment on a claim only if there is a showing that "there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." See generally Williams v. City of St. Louis, 783 F.2d 114, 115 (8th Cir. 1986). "[W]hile the materiality determination rests on the substantive law, it is the substantive law's identification of which facts are critical and which facts are irrelevant that governs." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986); see also Get Away Club, Inc. v. Coleman, 969 F.2d 664 (8th Cir. 1992). In applying this standard, the Court must view the evidence in the light most favorable to the non-moving party, giving that party the benefit of all inferences that may be reasonably drawn from the evidence. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 588-89 (1986); Tyler v. Harper, 744 F.2d 653, 655 (8th Cir. 1984), cert. denied, 470 U.S. 1057 (1985). However, a party opposing a motion for summary judgment "may not rest upon the mere allegations or denials of the . . . pleadings, but . . . by affidavits or as otherwise provided in [Rule 56], must set forth specific facts showing that there is a genuine issue for trial." Fed. R. Civ. P. 56(e).

2. Learned Intermediary Doctrine

Defendants argue many of Plaintiff's claims are barred by the learned intermediary doctrine. This doctrine provides that a pharmaceutical manufacturer has a duty to warn a physician of the risks involved with a pharmaceutical, and the physician then acts as a "learned intermediary" between the manufacturer and the physician's patient. See Ehlis v. Shire Richwood, Inc., 367 F.3d 1013, 1016 (8th Cir. 2004). "'Thus, a warning to the [physician] is deemed a warning to the patient; the manufacturer need not communicate directly with all ultimate users of prescription drugs.'" Id. (quoting Kirsch v. Picker Int'l, Inc., 753 F.2d 670, 671 (8th Cir.1985)). One of the underpinning rationales for the doctrine is the understanding that the patient is relying upon her

physician, and not the manufacturer, in deciding to use the drug in question. As a corollary to the doctrine, the failure of a drug manufacturer to provide the physician with an adequate warning of the risks associated with a prescription product is "not the proximate cause of a patient's injury if the prescribing physician had independent knowledge of the risk that the adequate warnings should have communicated." Doe v. Alpha Therapeutic Corp., 3 S.W.3d 404, 419-410 (Mo. 1999).

First, Defendants failed to identify undisputed facts demonstrating physicians were properly warned of the risks associated with Pondimin. While supplying "Dear Doc" letters dated from 1996 through 1997, they fail to show that Ms. Lachance's physician received these letters.[1] Moreover, Ms. Lachance began taking Pondimin before the letters were issued. Similarly, the labels were not altered until after Ms. Lachance began taking Pondimin. Finally, Defendants failed to present facts demonstrating her physician obtained knowledge about the risks of Pondimin outside of the information from the manufacturer. Without such facts, summary judgment cannot be granted on the issue of the learned intermediary doctrine. That is not to say the parties are barred from presenting such evidence at trial; all that can be said is the present record does not demonstrate undisputed facts entitling Defendants to judgment as a matter of law.

3. Reliance

Plaintiffs' common law claims of negligent misrepresentation, fraudulent misrepresentation, and breach of express warranty all require proof of reliance on a statement made by Defendants. E.g., Collins v. Missouri Bar Plan, 157 S.W.3d 726, 734 (Mo. Ct. App. 2005) (negligent misrepresentations); Mprove v. KLT Telecom, Inc.,135 S.W.3d 481, 489-90 (Mo. Ct. App.2004) (fraudulent misrepresentation);

[1]Defendants supplied these letters to the Court, but not in connection with its Motion for Partial Summary Judgment. Instead, they were attached to Defendants' separate Suggestions in Opposition to Plaintiffs' Motion for Summary Judgment, which was filed filed after this Motion. It was only through the Court's own digging through the many separate Summary Judgment Motions and exhibits that they were cross-applied to this argument.

Carpenter v. Chrysler Corp., 853 S.W.2d 346, 357 (Mo. Ct. App. 1993) (breach of express warranty). Plaintiff's statutory claim under the Missouri Merchandising Practices Act also requires proof of reliance. E.g., Taylor v. Richland Motors, 159 S.W.3d 492, 496 (Mo. Ct. App. 2005). Finally, Plaintiffs' claim of breach of implied warranty of fitness for a particular purpose requires them to establish a "seller" that had has reason to know any particular purpose for which the "goods" were required and that they relied on the seller's skill or judgment to select or furnish suitable goods. E.g., Heffernan v. Reinhold, 73 S.W.3d 659, 664 (Mo. Ct. App. 2002).

By Tedene Lachance' own account, she never read any material regarding the drug or side effects, read any advertising in making her decision to take the drug, or relied on any written or oral statements from Wyeth or American Home Products in "deciding" to "buy" Pondimin. Def. Exhibit C. The record conclusively demonstrates Plaintiff cannot establish the reliance required for these claims. Therefore, summary judgment is granted on Plaintiff's claims of negligent misrepresentation, fraudulent misrepresentation, breach of express warranty, breach of implied warranty and violation of unfair trade practices.

4. Negligence Per Se

Plaintiffs allege Defendants failed to comply with the statutory and regulatory provisions governing prescription medications and this failure constituted negligence per se. Four requirements must be met to establish a claim for negligence per se: 1) a violation of a statute or ordinance; 2) the injured party must be within the class of persons intended to be protected by the statute or ordinance; 3) the injury complained of must be of the nature that the statute or ordinance was designed to prevent; and 4) the violation of the statute or ordinance must be the proximate cause of the injury. See Lowdermilk v. Vescovo Building and Realty Co., Inc., 91 S.W.3d 617, 628 (Mo. Ct. App. 2002).

Defendants rely on the Supreme Court's decision in Buckman v. Plaintiff's Legal Committee, 531 U.S. 341 (2001). Specifically, Defendants point to the footnote stating

"[t]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the *medical device provisions*: '[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.'" Buckman at 349 (emphasis added). This case is distinguishable because Buckman deals specifically with the Medical Devices Act, and Pondimin is not a medical device governed by that statutory scheme.

The Court concedes Plaintiffs' claims may be preempted by the FDA. However, Defendants cite no specific authority and the Court's research did not uncover any that would specifically preempt Plaintiffs' claim of negligence per se based on noncompliance. Defendants' Motion for Summary Judgment on negligence per se is denied.

5. Failure to Test

Plaintiffs claim Defendants failed to conduct adequate preclinical and clinical testing. They further allege Defendants failed to conduct post-marketing surveillance of their product. Relying solely on Buckman, Defendants claim Plaintiffs are barred from making a failure to test claim. The same failings discussed above in Section 4 apply to the failure to test claim. Therefore, Defendants' Motion for Summary Judgment on Failure to Test is denied.

6. Strict Liability

The essential elements of a strict product liability claim are (1) the defendant sold a product in the course of its business; (2) the product was then in a defective condition, unreasonably dangerous when put to a reasonably anticipated use; (3) the product was used in a manner reasonably anticipated; and (4) the plaintiff was damaged as a direct result of such defective condition as existed when the product was sold." Lay v. P & G Health Care, Inc., 37 S.W.3d 310, 325 (Mo. Ct. App. 2000.) Defendants argue that

Plaintiffs' claim for strict liability should fail based upon Comment k of Restatement (Second) Torts § 402A, which states in part "There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs." Defendants claim Pondimin is "unavoidably unsafe." A knife is an unavoidably unsafe product because its useful and desirable to society but cannot be produced without some risk. Defendants claim that because obesity is an epidemic in this country and Pondimin assists in the treatment of obesity, its benefit outweighs its risk.

The issue Defendants present is one of fact, and must be decided by the jury. Certainly, undisputed facts in an appropriate case (e.g., one involving the aforementioned knife) would justify summary judgment. This is not such a case.

In one of its early cases discussing strict liability, the Missouri Supreme Court held that "the concept of unreasonable danger, which is determinative of whether a product is defective in a design case, is presented to the jury as an ultimate issue without further definition." Nesselrode v. Executive Beechcraft, Inc., 707 S.W.2d 371, 378 (Mo. 1986) (en banc). "The jury gives this concept content by applying their collective intelligence and experience to the broad evidentiary spectrum of facts and circumstances presented by the parties." Id. Subsequent to Nesselrode, Missouri courts have never added additional "gloss" to the concept of unreasonable danger. E.g., Newman v. Ford Motor Co., 975 S.W.2d 147, 152 (Mo. 1998) (en banc); Miller v. Varity Corp., 922 S.W.2d 821, 825 (Mo. Ct. App. 1996); see also Drabik v. Stanley-Bostich, Inc., 997 F.2d 496, 506 (8th Cir. 1993) ("The Missouri Supreme Court has been resistant to establishing a strict definition for the term unreasonably dangerous.")

Despite the fact that Missouri law does not rely upon a single factor as the standard of unreasonable dangerousness, it may be appropriate to provide guidance to the jury on this matter. E.g., Hagen v. Celotex Corp., 816 S.W.2d 667, 674 (Mo. 1991) (en banc); Drabik, 997 F.2d at 506 & n.5. Indeed, the topic in Hagen involved an instruction based on comment k. The Court would consider providing the jury a non-exhaustive list of factors it can consider in evaluating whether Defendants product was unreasonably dangerous, including an instruction based on comment k. The parties

should keep this in mind when proposing their jury instructions, and should include a proposal that accomplishes this purpose.

III. CONCLUSION

For the foregoing reasons, Defendants' Motion for Summary Judgment is granted in part and denied in part. Defendants are granted summary judgment on Plaintiffs' claims of negligent misrepresentation, fraudulent misrepresentation, breach of express warranty, breach of implied warranty and violation of unfair trade practices. Summary Judgment is denied on Plaintiffs' claims of failure to warn, failure to test, negligence, negligence per se and strict liability. Those claims remain for trial.

IT IS SO ORDERED.

Date: January 13, 2006

/s/ Ortrie D. Smith
ORTRIE D. SMITH, JUDGE
UNITED STATES DISTRICT COURT